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K071759

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510(k) SUMMARY

Live Tissue Connect Inc.'s VAD System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Live Tissue Connect, Inc.
2813 Gaviota Street
Los Olivos, CA 93441

Phone: 805-686-0937
Facsimile: 805-686-5399

Contact Person: Frank D. D'Amelio

Date Prepared: February 10, 2007

Name of Device and Name/Address of Sponsor

LTC VAD System
Live Tissue Connect, Inc.
500 North Shoreline
Corpus Christi, Texas 78741

Common or Usual Name

Electrosurgical Bipolar Device

Classification Name

Electrosurgical Cutting and Coagulation Device and Accessories

Predicate Devices

LigaSure Vessel Sealing System (K981916)
LigaSure Advance (K063195)
Gyrus General Purpose Electrosurgical System (K050550)
Gyrus OPEN FORCEPS (K024286)

Intended Use / Indications for Use

The LTC VAD.400 is an electrosurgical generator coupled with designated LTC electrosurgical instruments for bipolar tissue fusion. The LTC VAD.400 electrosurgical generator and designated LTC electrosurgical instruments (i.e., "the VAD System") are intended for use in open general surgical procedures where ligation of vessels and ducts is desired and as an alternative to mechanical clamping (clips or staples) or suturing. The LTC VAD System can be used on vessels up to 7mm in diameter, on ducts up to 2mm in diameter, and tissue bundles as large as will fit in the jaw electrodes of the instrument.

The LTC VAD system has not yet been tested for use in tubal sterilization or tubal coagulation for sterilization procedures; therefore, the company does not recommend the use of the LTC VAD system for such procedures. In addition, LTC recommends against the use of the VAD System for male circumcisions.

Technological Characteristics

The LTC VAD System consists of: a bipolar electrosurgical generator and two distinct and dedicated electrosurgical instruments.

Performance Data

Bench, animal and clinical testing was conducted using the LTC VAD System. In all instances, the LTC VAD System functioned as intended and all results observed were as expected.

Substantial Equivalence

The LTC VAD System is as safe and effective as the predicate devices. The LTC VAD System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the LTC VAD System and its predicate devices raise no new issues of safety or effectiveness. Thus, the LTC VAD System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2008

Live Tissue Connect, Inc.
% Hogan & Hartson
Mr. Howard M. Holstein
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K071759
Trade/Device Name: LTC VAD System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 1, 2008
Received: May 1, 2008

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K071759

Device Name: LTC VAD System

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071759